

**(19) World Intellectual Property Organization
International Bureau**



A standard linear barcode is located at the bottom of the page, spanning most of the width. It is used for document tracking and identification.

(43) International Publication Date
14 August 2003 (14.08.2003)

PCT

(10) International Publication Number
WO 03/065933 A1

(51) International Patent Classification⁷:	A61F 2/06	(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, IU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YA, ZA, ZM, ZW.
(21) International Application Number:	PCT/US03/01701	
(22) International Filing Date:	17 January 2003 (17.01.2003)	
(25) Filing Language:	English	
(26) Publication Language:	English	
(30) Priority Data:		
10/071,635	7 February 2002 (07.02.2002)	US
(71) Applicant:	SENTIENT ENGINEERING & TECHNOLOGY, L.L.C. [US/US]; 4260 N. Fanning Drive,	(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW); Eurasian patent (AM, AT, BE, BY, KG, KZ, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SI, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

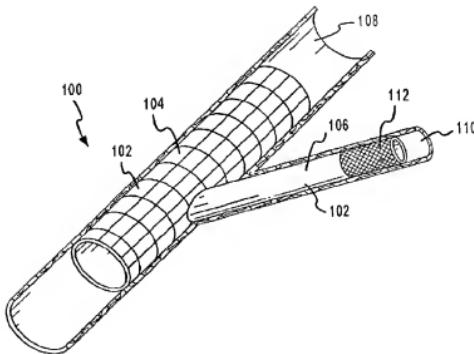
(72) **Inventor:** LAGUNA, Alvaro; 4260 N. Fanning Drive, Flagstaff, AZ 86004 (US)

(74) Agents: JAROSIK, Gary, R. et al.; Alzheimer & Gray, 10 S. Wacker Drive, Suite 4000, Chicago, IL 60606 (US).

Published:

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: APPARATUS AND METHODS FOR CONDUITS AND MATERIALS



(57) Abstract: The present invention provides apparatus and methods for a conduit (102), such as an implantable conduit (102) for a vessel (108). The conduit (102) may comprise a main member (104) and a side-branch member (106). The conduit (102) may be implanted with the side-branch member initially disposed within the main member (104). When positioned, the side-branch member (106) may then be extended from within the main member (104) and into a vessel side-branch. The materials for the conduit may include circumferentially distensible and/or low recoil materials.

APPARATUS AND METHODS FOR CONDUITS AND MATERIALS

Field of Invention

5 The present invention generally relates to medical devices.

Background of the Invention

Vascular disease, the disease of blood vessels, is one of the leading causes of death in the western world. There are two main categories of vascular disease, aneurysmal and occlusive. Aneurysmal disease results in the weakening of blood vessels 10 causing them to dilate excessively and in some instances ultimately rupture. Occlusive disease results in blockage of blood vessels, limiting the conveyance of blood.

Stents and stent-grafts are commonly used to treat diseased blood vessels and other tubular structures within the body. Stents and stent-grafts have been employed successfully to either reinforce afflicted blood vessels in the case of aneurysmal disease, 15 or to radially open and support blood vessels for the purpose of restoring blood flow in the case of occlusive disease. To such ends, stents and stent-grafts have been implanted in the coronary as well as peripheral vasculature. Additionally, stents have been implanted within the neurovasculature, and in other bodily conduits such as the urinary tract, the bile duct, and the tracheo-bronchial tree.

20 Current stent-grafts intended for the treatment of aneurysmal disease are generally available in various diameters. Several devices are available in bifurcated configurations. These bifurcated devices are typically designed for use within the aortic bifurcation, where the abdominal aorta branches into the right and left common iliac arteries. Frequently, this anatomic region is riddled by aneurysmal disease, causing a 25 potentially life-threatening situation. In an effort to treat the potentially life-threatening situation, bifurcated stent-grafts are implanted within the aneurysmal regions of the afflicted vessels, essentially forming a new blood flow conduit within the aneurysm, and isolating the aneurysm from blood flow and the associated blood pressure. This is referred to as excluding the aneurysm. Similarly, aneurysms of the aortic arch and the thoracic 30 aorta are also common.

Conventional stent-grafts, however, do not accommodate side-branches of the aorta. Once an aneurysm has been excluded, the entire diseased section of the afflicted vessel is isolated from normal blood flow. This isolation includes any side-branches emanating from the aorta within the afflicted region. While this may be a good outcome 35 from the perspective of managing a potentially life-threatening situation, such isolation

from blood flow can lead to ischemic complications in certain areas of the body. For example, emanating from the abdominal aorta distal to the renal arteries are lumbar arteries, testicular/ovarian arteries, and the inferior mesenteric artery, which provides blood to the left transverse colon, descending and sigmoid colons, and rectum. Many 5 aneurysms of the abdominal aorta include the origin of the inferior mesenteric artery. After successful exclusion of these aneurysms, the left transverse colon, descending and sigmoid colons, and rectum rely on collateral circulation for their blood supply. For many patients, the collateral circulation is sufficient, but for others it is not, resulting in complications involving the various organs.

10 Additionally, many aorto-iliac aneurysms involve the abdominal aorta as well as substantial portions of either (or both) of the common iliac arteries. In many cases, the disease extends along the common iliac artery past the bifurcation point where the common iliac branches into the external and the internal iliac arteries. In such cases, the 15 endoluminal treatment of the aneurysm may require extending the stent-graft device into the external iliac artery, isolating the internal iliac artery from normal blood supply and leaving large portions of the pelvic area and leg reliant on collateral circulation for their blood supply. For example, the hypogastric artery, which supplies blood to the pelvic area, branches from the internal iliac artery. Isolation of the hypogastric artery from normal blood flow can result in buttock claudication, impotence, and colon ischemia.

20 Aneurysms of the aortic arch, for example, can be especially difficult to treat using currently available stent-graft devices. Three major vessels originate from the aortic arch: the brachiocephalic, the left common carotid, and the subclavian artery. These vessels provide critical blood flow to the head, neck and arms. If a stent-graft device is endoluminally implanted to treat aortic arch aneurysms, adjunctive measures 25 must be taken to ensure adequate blood supply to the body parts (especially the brain) that receive their blood supply from the affected vessels.

30 On the other hand, while in some instances isolation of a side-branch vessel via aneurysm exclusion results in compromised blood supply due to inadequate collateral circulation, in situations of abundant collateral circulation, the presence of a side-branch vessel can actually hinder aneurysm exclusion. Retrograde blood flow from side-branches emanating within the aneurysmal region can maintain blood pressure within the aneurysm, often resulting in leakage between the stent-graft device and the afflicted vessel.

Like stent-grafts intended for the treatment of aneurysmal disease, stent-grafts intended for the treatment of occlusive disease are generally tubular and available in various diameters. Such stent-graft devices offer the advantage of providing a physical barrier, which impedes reproliferation of the disease through the wall of the implanted device. The treatment of vessels afflicted by occlusive disease at points of bifurcations, however, can be problematic due to the unpredictability of the vascular remodeling associated with balloon angioplasty and stent-graft implantation. In many instances, side-branches can be compromised as a result of plaque redistribution from the main vessel into the origin of the side-branch, resulting in stenosis of the side-branch.

10

Summary of the Invention

A prosthetic conduit according to various aspects of the present invention includes a main member and a side-branch member. The main member may be configured to reside in a main vessel. For example, one embodiment comprises at least one stent, at least one main graft, and at least one opening in its side wall. The side-branch member is 15 suitably configured to reside in a side-branch vessel, and may include, for example, at least one side-branch stent and at least one side-branch graft. The side-branch member is connected to the main member at the side wall opening. The side-branch member may be configured to be extendable through the opening to deploy the stent-graft.

The side-branch member may be located within the main member before and 20 during delivery of the stent-graft to a desired location within a vessel. Once the main member is placed in a desired location, the side-branch member may be pushed or pulled out of the main member and into the desired side-branch vessel. The stent-graft may be inserted into a vessel at one access site and placed at a desired location within the vessel by any suitable method, such as using balloon catheters, guidewires, and/or a constraining 25 sheath with a push tube.

Materials according to various aspects of the present invention that may be used in the main member, the side-branch member, and/or other elements are distensible. In particular, the materials may be treated to circumferentially distend without significant foreshortening and/or recoil.

Brief Description of Exemplary Drawings

Additional aspects of the present invention are evident upon reviewing the non-limiting embodiments described in the specification and the claims, in conjunction with the accompanying figures, wherein like numerals designate like elements:

5 Figure 1 is a perspective view of an exemplary embodiment of a prosthetic conduit with a side-branch shown within a cross-section of a vessel with a side-branch.

Figure 2 is a perspective view of an exemplary embodiment of a main member of a prosthetic conduit.

10 Figure 3 is a perspective view of an exemplary embodiment of a side-branch member.

Figure 4 is a cross-sectional view of an exemplary embodiment of a prosthetic conduit, shown with an apparatus for delivery, including a main guidewire, a main balloon catheter, a side-branch guidewire and a side-branch balloon catheter.

15 Figure 5 is a flow chart illustrating an exemplary delivery and deployment process.

Figure 6 is a perspective view of an exemplary embodiment of a prosthetic conduit, with the distal end of the main member inflated by a balloon catheter and the side-branch retracted, shown within a cross-section of a vessel with a side-branch.

20 Figure 7 is a cross-sectional view of an exemplary embodiment of a prosthetic conduit, with the distal end of the main member inflated with a balloon catheter and the side-branch member partially pushed out from within the main member.

Figure 8 is a perspective view of an exemplary embodiment of a prosthetic conduit, shown within a cross-section of a vessel with a side-branch, with the main member fully expanded and the side-branch member not fully expanded.

25 Figure 9 is a cross-sectional view of an exemplary embodiment of a prosthetic conduit with a deployment tube.

Figure 10 is a cross-sectional view of an exemplary embodiment of a prosthetic conduit wherein the main member is self-expanding, shown with an apparatus for delivery including a constraining sheath, a push tube, a side-branch balloon catheter, and 30 a side-branch guidewire.

Figure 11 is a cross-sectional view of an exemplary embodiment of the distal end of a constraining sheath configured to deliver a prosthetic conduit with a self-expanding main member within a vessel.

5 Figure 12 is an end-on view of the distal end of an exemplary embodiment of the constraining sheath used to deliver a prosthetic conduit with a self-expanding main member within a vessel.

Figure 13 is a cross-sectional, end-on view of an exemplary embodiment of a push tube device configured to deliver a prosthetic conduit with a self-expanding main member within a vessel.

10 Figures 14A-B are a flow chart illustrating an exemplary preparation process for a prosthetic conduit.

Figure 15 is a graph illustrating distensibility data for a distensible tube and a non-distensible tube.

15 Elements in the figures are illustrated for simplicity and clarity and have not necessarily been drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help to improve understanding of embodiments of the present invention.

Detailed Description of Exemplary Embodiments

Various aspects and features of the present invention may be described in terms of 20 functional components and steps. Such functional components and steps may be realized by any number of elements and/or steps configured to perform the specified functions. For example, the present methods and apparatus may employ conduits and supports, like 25 grafts and stents, which may carry out a variety of functions in various embodiments, applications, and environments. In addition, the present methods and apparatus may be practiced in conjunction with any number of procedures and systems, and the apparatus and methods described are merely exemplary applications for the invention. Further, the present methods and apparatus may employ any number of techniques, conventional or otherwise, for placement, use, manufacturing, and the like. Such general techniques that may be referred to are not described in detail.

30 A prosthetic conduit system according to various aspects of the present embodiment is implantable within an organism, such as a human being or animal. The

prosthetic conduit may comprise any conduit, for example for use in blood vessels, bile ducts, the urinary tracts, or any other conduit in the organism. For example, a prosthetic blood vessel structure may comprise a stent, a graft, a stent-graft, or other implantable structure. The prosthetic blood vessel may be configured, however, in any manner 5 according to the particular application or environment, including variations in dimensions, shape, materials, flexibility, and the like. Various aspects of the present invention may also be applicable to other devices, such as other medical devices and other conduits.

Referring to Figure 1, a prosthetic conduit system 100 according to various 10 aspects of the present invention includes a prosthetic conduit 102, such as a stent-graft. In various embodiments, the prosthetic conduit 102 includes a side-branch, and is suitable for placement in a main vessel 108 with a side-branch vessel 110. For example, the prosthetic conduit 102 may include a main member 104 and a side-branch member 106. Each of the main member 104 and the side-branch member 106 may include one or more 15 stents and one or more sections of graft material.

Although the present exemplary embodiment comprises the stent-graft having one main member 104 with one side-branch member 106, the various configurations of a prosthetic conduit are not so limited, and may be configured in any suitable manner for the particular application and/or environment. For example, the main member 104 may 20 have a bifurcation at one or both ends, two or more side-branch members 106 may be included, and the like. The prosthetic conduit 102 may include one continuous piece of graft material and multiple stents, one continuous stent-graft, or any suitable combination of one or more stents and/or one or more pieces of graft material. Furthermore, the side-branch member 106 may be configured to branch from the main member at any suitable 25 angle. The side-branch member 106 may be further configured to adapt to a range of angles to allow for placement into multiple different configurations of main vessel 108 and side-branch vessel 110.

Similarly, the prosthetic conduit 102 may have any suitable size or combination of 30 sizes. For example, the main member 104 may be configured for placement within a relatively large main vessel 108, such as the abdominal aorta, while side-branch member 106 may be configured for placement within a relatively small side-branch vessel 110, such as a renal artery. In another embodiment, both the main member 104 and side-branch member 106 may be relatively small, for example if the prosthetic conduit is

configured to be placed in human coronary arteries. Thus, the prosthetic conduit 102, including the main member 104 and side-branch member 106, may have any suitable dimensions.

In a first exemplary embodiment, the entire length of the main member 104 5 comprises a combination of stent and graft material, while the side-branch member 106 includes a graft material along its entire length with a side-branch stent 112 located at its distal end. In another embodiment, each of the main member 104 and the side-branch member 106 comprises a single continuous piece of graft material and multiple stents. Alternatively, the prosthetic conduit 102 may comprise one continuous stent-graft 10 comprised of a single graft and a single stent. Further, the prosthetic conduit 102 may comprise one or more grafts with no stents or one or more stents with no graft sections. Thus, the prosthetic conduit 102 may comprise various combinations of one or more stents and one or more pieces of graft material.

Referring now to Figure 2, the main member 104 may be configured to provide a 15 main blood flow conduit and may include a support for the conduit to keep it open. Further, the main member 104 may be configured to provide flow to and/or from the side-branch member 106. In the present embodiment, the main member suitably has a generally tubular configuration with open ends, and comprises a main stent 200, a main graft 202, and at least one side opening 204. The main stent 200 provides support to 20 maintain the desired position and/or configuration of the prosthetic conduit 102. The main stent 200 may be a single stent or a plurality of stents, and may be present along the entire length of the main member 104, or only in sections, and may extend beyond the length of the main graft 202. The main stent 200 may be incorporated into the main member 104 in any location by any suitable method, or may be installed separately. The 25 main stent 200 may be deployed in any appropriate manner, such as balloon expansion, self-expansion, or any suitable combination of both, and may be constructed of a variety of materials or combinations, such as, but not limited to, metals or alloys (stainless steel, titanium, tantalum, nitinol and the like), polymers, carbon, ceramics and the like.

Alternative embodiments of the main member 104 may also include other or 30 additional mechanisms for supporting and/or securing the main member 104 to a surrounding organism vessel 108. Stents or other suitable devices, for example, may be utilized to provide additional support and/or strength to the main member 104, such that the main stent 200 may be supplemented, replaced, or omitted altogether. Further, the

main member 104 may be secured in position by an adhesive on at least a portion of the main member 104 outer surface (or the inner surface of the attachment site), a set of barbs or pins attached to the main member 104 and engaging the surrounding tissue, and the like.

5 The main graft 202 provides a conduit for fluid flow through the main member 104. The main graft 202 may be comprised of any suitable material, such as a biocompatible material, or combination of materials, such as, but not limited to, polyester, polyether sulfone, polyethylene, polytetrafluoroethylene (PTFE), polyurethane and the like. Further, the materials may be configured or treated in any manner to achieve 10 selected characteristics. For example, the material may be treated in accordance with the disclosure of U.S. Patent No. 5,800,522, issued September 1, 1998, to Campbell, et al. Moreover, the main graft 202 may be comprised of various forms or combinations of forms, such as, but not limited to, extruded tubing, braided tubing, textile tubing, tubing created from the wrapping and bonding of thin films, and the like. The main graft 202 15 may be of any suitable porosity.

In the present embodiment, the main graft 202 includes a thin, flexible material, such as polyethylene. In the present embodiment, the main graft 202 is not treated, as described below, to be circumferentially distensible. The main graft 202 may, however, 20 comprise any suitable material, including a material that may be distended with minimal foreshortening and recoil to conform to the organism vessel 108, 110, the stents 112, 200, or other characteristic. If the main graft 202 material is distensible (for example, as described and defined in U.S. Patent No. 5,800,522, issued September 1, 1998, to Campbell, et al.), the graft material may be circumferentially distended along its entire 25 length, or in selected portions. Various coatings or treatments can be applied to either the main stent 200, the main graft 202, or both, to render the main member 104 more biocompatible (pyrolytic carbon, hydrogels and the like) and/or to provide for the elution of drugs (heparin, anti-platelet agents, platelet derived growth factors, antibiotics, steroids and the like). Additionally, various coatings or treatments may be applied to either the main stent 200, the main graft 202, or both, to render the main member 104 radioactive.

30 The main graft 202 may be configured to be placed on either the inner surface or the outer surface of the main stent 200, or in any suitable position relative to the inner or outer surface of the main stent 200. The main stent 200 and main graft 202 may be connected before placement into a vessel, or the main stent 200 and main graft 202 may

be inserted into a vessel separately and connected within the vessel. In either case, the main graft 202 may be attached to the main stent 200 by any suitable mechanism.

The main member 104 may include a radiopaque material to enhance the visibility of the main member 104. For example, the main stent 200 or the main graft 202 may be wholly or partially comprised of radiopaque materials. Alternatively, radiopaque markers 206 may be incorporated into the main graft 202 or the main stent 200, either throughout the structure or at one or more locations.

The side-branch member 106 facilitates flow between the main member 104 and a side-branch vessel 110. For example, referring to Figure 3, the side-branch member 106 may have a generally tubular configuration with an open proximal end 308 and an open distal end 306. The side-branch member 106 suitably comprises a side-branch graft 310 for facilitating fluid flow between the main member 104 and the open distal end 306. The side-branch member 106 may also include a side-branch stent 112, for example to support the distal end 306. In the present exemplary embodiment, the side-branch member 106 includes a straight section 300, a conical section 302, and an attachment area, such as a flange 304.

Similar to the main member 104, the side-branch member 106 may suitably comprise a combination of one or more stents, such as the side-branch stent 112, and one or more sections of graft material, such as the side-branch graft 310. The side-branch member 106 may include any suitable combination of stents (if desired) and graft material. For example, one or more stents may be used in one side-branch member 106, and/or stents may be placed entirely within the length of the side-branch graft 310 or may extend beyond the length of the side-branch graft 310, protruding further into the side-branch vessel 110.

The side-branch stent retains the side-branch graft 310 in an open position and/or secures the position of the side-branch graft 310. The side-branch stent 112 may be positioned in any suitable manner, such as by placing the stent in a desired position and expanding the stent within the organism vessel 110. The side-branch stent 112 may be balloon expandable, self-expanding, or any combination, and may be constructed from one or more of a variety of suitable materials, such as, but not limited to, metal or alloys (stainless steel, titanium, tantalum, nitinol and the like), polymers possessing varying degrees of bioabsorption and biodegradation, carbon, ceramics, and the like.

The side-branch stent 112 may be configured such that it is in contact with the inner or outer surface of the side-branch graft 310 or a combination of both. The side-branch stent 112 may engage or be attached to the side-branch graft 310 in any appropriate manner. For example, in one embodiment, the side-branch stent 112 may be 5 inserted into a vessel as a separate piece and may be attached to the side-branch graft 310 within the side-branch vessel 110. In other embodiments, the side-branch stent 112 is configured to be implanted at the same time as the side-branch graft 310.

The side-branch graft 310 may be constructed from one or more of a variety of suitable materials, such as, but not limited to, polyester, polyether sulfone, polyethylene, 10 polytetrafluoroethylene, polyurethane and the like. The side-branch graft 310 may be of any suitable porosity. In the present embodiment, the side-branch graft 310 includes a thin, strong, flexible, and/or kink resistant material. For example, the side-branch graft 310 suitably includes a material, such as treated polyethylene, that may be circumferentially distended without significant foreshortening and/or recoil. The graft 15 material may be circumferentially distensible along its entire length, or in selected portions. Further, the materials may be configured or treated in any manner to achieve selected characteristics. For example, the material may be treated in accordance with the disclosure of U.S. Patent No. 5,800,522, issued September 1, 1998, to Campbell, et al. Furthermore, side-branch graft 310 may be comprised of various forms or combinations 20 of forms, such as, but not limited to, extruded tubing, braided tubing, textile tubing, tubing created from the wrapping and bonding of thin films, and the like.

Various coatings or treatments may be applied to render the side-branch stent 112 and/or the side-branch graft 310 more biocompatible (pyrolytic carbon, hydrogels and the like) and to provide for the elution of drugs (heparin, anti-platelet agents, platelet derived 25 growth factors, antibiotics, steroids and the like). Various coatings or treatments may be applied to render the side-branch stent 112 and/or the side-branch graft 310 radioactive. Further, the side-branch member 106 may include one or more areas, such as portions of the graft 310 and/or the side-branch stent 112, that are radiopaque. For example, the side-branch stent 112 may be constructed from one or more radiopaque materials and/or one or 30 more radiopaque markers (not shown) may be placed on the graft 310 or the side-branch stent 112 materials at one or more locations along the side-branch member 106.

The side-branch member 106 is connected to the main member 104 to allow fluid flow between the two components. The side-branch member 106 is suitably connected

via its proximal end 308 to the side opening 204 of the main member 104. In the present embodiment, the conical section 302 has a diameter that is larger at the proximal end 308 and tapers as it approaches the straight section 300. The proximal end 308 may be configured to fit within, around, or in any other suitable configuration with the side opening 204 of the main member 104.

5 The proximal end 308 may further include a mechanism, such as the attachment area including the flange 304, for facilitating attachment of the side-branch member 106 to the side opening 204 of the main member 104. The flange 304 may be bonded in any appropriate manner to the outer surface, the inner surface, or any other appropriate 10 portion of the main member 104. The flange 304 may be incorporated into the proximal end 308 to provide a surface that may be easily positioned against and bonded to the perimeter of the side opening 204, for example to effect a liquid-tight and strong connection.

15 The side-branch member 106 may be configured for attachment to the main member 104 at any suitable angle. The prosthetic conduit 102 may be provided in multiple angular and structural combinations, enabling a variety of configurations. Furthermore, the side-branch member 106, or a portion thereof, may be configured to 20 allow flexibility, such that prosthetic conduit 102 may be used in a variety of different angles between the main vessel 108 and the side-branch vessel 110. For example, in one embodiment, a particular prosthetic conduit 102 may be placed or used in vessels having anywhere from a 25-degree angle to a 45-degree angle. Other embodiments may accommodate other angles and/or greater or lesser ranges of angles.

25 The prosthetic conduit system 100 according to various aspects of the present invention may be placed directly at a selected site. Alternatively, the prosthetic conduit system 100 may be introduced at a first site and delivered to the desired location using a delivery system. The prosthetic conduit system 100 may also include a deployment system for deploying the prosthetic conduit 102 at the selected site. The delivery system and/or the deployment system may be integrated into or independent from the prosthetic conduit 102. The delivery system suitably places and stabilizes the prosthetic conduit 102 30 at a desired location. The deployment system suitably configures and secures the prosthetic conduit 102 for operation following delivery.

The delivery system for positioning the prosthetic conduit 102 in the desired position may comprise any suitable delivery system, such as, but not limited to, one or more balloon catheters, guidewires, introducer sheaths, guiding catheters, push tubes, and/or constraining sheaths. Referring to Figure 4, an exemplary integrated delivery and deployment system according to various aspects of the present invention comprises a main guidewire 408, a main balloon catheter 400, a side-branch guidewire 410, and a side-branch balloon catheter 406. The main guidewire 408 and the side-branch guidewire 410 may comprise any suitable guides to facilitate navigation of the prosthetic conduit 102 to a desired location and extension of the side-branch member 106. The guidewires 408, 410 are advanced through the organism vessels to guide the prosthetic conduit 102 to the desired location.

The balloon catheters 400, 406 move the prosthetic conduit 102, secure the prosthetic conduit 102 in position, and/or deploy the prosthetic conduit 102. The main balloon catheter 400 and side-branch balloon catheter 406 may be conventional balloon catheters, and may possess varying degrees of compliance. For example, in some embodiments the balloon catheters 400, 406 may be highly compliant, such as embolectomy balloon catheters, while in other embodiments the balloon catheters 400, 406 may be non-compliant or semi-compliant high-pressure balloon dilation catheters. Additionally, the balloon catheters 400, 406 may be either over-the-wire or rapid-exchange balloon catheters.

The balloon catheters 400, 406 are configured to engage the guidewires 408, 410 so that the balloon catheters 400, 406 may move along the guidewires. The balloon catheters 400, 406 are also configured to engage the prosthetic conduit 102 to facilitate movement and deployment of the prosthetic conduit 102. For example, in the present embodiment, the distal end 402 of the main member 104 may be releasably attached, by any suitable mechanism, to the main balloon catheter 400, and the distal end 306 of the side-branch member 106 may be releasably attached to the side-branch balloon catheter 406.

The prosthetic conduit 102 may be equipped with the delivery system and/or deployment system prior to implantation. Alternatively, the delivery system may be provided at the time of implantation. For example, the main balloon catheter 400 may be integrated into the prosthetic conduit 102 at the time of manufacture, or may be connected to the prosthetic conduit 102 at the time of implantation. Similarly, the side-branch

balloon catheter 406 may be omitted during the initial introduction of the prosthetic conduit 102 into the vasculature. The relatively small profile of the side-branch guidewire 410 may be advantageous in certain situations compared to the side-branch balloon catheter 406 or a tube. Thus, installation techniques and conduits may be selected 5 according to the particular configuration, application, or situation.

Referring to Figure 5, to place the prosthetic conduit 102 at a desired location, the main guidewire 408 may be introduced into the vasculature and navigated into the main vessel 108 (step 510). The main balloon catheter 400, releasably attached to the distal end 402 of the main member, may be advanced along the main guidewire 408, advancing 10 with it the prosthetic conduit 102 (step 512). To enhance accuracy of placement of the prosthetic conduit 102, the side-branch guidewire 410 may be used to align the side opening 204 of the main member 104 with the origin of the side-branch vessel 110 (step 514).

When the prosthetic conduit 102 is placed at a desired location, it may be secured 15 in the desired position (step 516), for example using the balloon catheters 400, 406. For example, referring to Figure 6, upon properly positioning the prosthetic conduit 102, the main member distal end 402 may be secured in position, for example by inflating the main balloon catheter 400 while the side-branch member 106 remains retracted. The main member distal end 402 may be expanded by the main balloon catheter 400 until the 20 distal end 402 contacts the inner surface of main vessel 108. Expansion of the main member distal end 402 tends to stabilize the prosthetic conduit 102 so that the side-branch member 106 may be extended from the main member 104 and into the side-branch vessel 110. The remainder of the main member 104 may also be fully expanded along its entire length, either by one or more balloon catheters, by self-expansion, or by other suitable 25 methods or apparatus.

After the position of the prosthetic conduit 102 has been secured, it may be deployed for operation. Any suitable deployment system may be employed to deploy the prosthetic conduit 102, and the deployment system may be configured in any suitable manner to configure the prosthetic conduit 102 for operation. The prosthetic conduit 102 30 may be equipped with the deployment system prior to implantation or at the time of implantation.

In the present embodiment, the prosthetic conduit 102 is configured so that the side-branch member 106 is initially located within the main member 104 for delivery into a vessel. Such a configuration may ease delivery of the prosthetic conduit 102 into one or more vessels. Thus, the deployment system is suitably configured to extend the side-
5 branch member 106 from within the main member 104 and into the side-branch vessel 110, and expand the main member 104 and side-branch member 106 to facilitate fluid flow. In particular, the deployment system includes the main guidewire 408, the side-
branch guidewire 410, the main balloon catheter 400, and the side-branch balloon catheter 406. When the prosthetic conduit 102 is properly positioned within the vasculature by the
10 delivery system, the side-branch balloon catheter 406 may be moved along the side-
branch guidewire 410 to the distal end 306 of side-branch member 106, unless the side-
branch balloon catheter 406 was placed simultaneously with the prosthetic conduit 102. The side-branch member 106 may be deployed by releasably attaching the side-branch
15 balloon catheter 406 to the side-branch member 106 to extend the side-branch member
106 into the side-branch vessel 110. The side-branch member 106 is then suitably
extended along the side-branch guidewire 410 and secured using the side-branch balloon
catheter 406.

The side-branch balloon catheter 406 may be attached to the side-branch member
106 in any suitable manner, such as by crimping side-branch stent 112 and the
20 surrounding graft material onto side-branch balloon catheter 406 to releasably attach side-
branch balloon catheter 406 to the side-branch member 106. In the present embodiment,
the side-branch balloon catheter 406 may be positioned within the side-branch stent 112
and inflated to a pressure high enough to engage the side-branch stent 112, but low
enough to avoid substantial expansion of the side-branch stent 112.

25 Referring to Figure 7, after releasably attaching the distal end 306 of the side-
branch member 106 to the side-branch balloon catheter 406, the side-branch balloon
catheter 406 and the side-branch member 106 may be advanced along the side-branch
guidewire 410 to a desired location, thus extending the side-branch member 106 into the
side-branch vessel 110 (step 520). After extending the side-branch member 106, the side-
30 branch stent 112 is in a position to be expanded to secure the side-branch member 106 in
position and facilitate flow. In an alternative embodiment, the side-branch stent 112 may
be installed separately, after the side-branch member 106 has been otherwise pushed or
pulled from inside the main member 104.

Referring to Figure 8, the side-branch stent 112 may then be expanded to contact or adhere to the inner surface of the side-branch vessel 110 (step 522). For example, the side-branch balloon catheter 406 is inflated to a selected pressure and for a selected duration, causing the distal end of side-branch member 106 encompassing side-branch stent 112 to circumferentially distend. The pressure is then suitably released and side-branch balloon catheter 406 may be moved toward the proximal end of the side-branch member 106. The side-branch balloon 406 is inflated again, causing the adjacent region of the side-branch member 106 to distend. This process of circumferential distention may be repeated until the side-branch balloon catheter 406 distends the entire length of the side-branch member 106 (step 524). When the main member 104 is placed and fully dilated and the side-branch member 106 is fully extended and distended, the prosthetic conduit 102 is fully deployed and operational.

The balloon catheters 400, 406 facilitate delivery of the prosthetic conduit 102 and extension of the side-branch member. Any suitable system, however, may be used to deliver and deploy the prosthetic conduit 102 and side-branch member 106. For example, a snare may be used to grasp the distal end 306 of side-branch member 106 and unfold it, either by pushing or pulling. Alternatively, referring to Figure 9, the deployment system may include a deployment tube 906, which may be similar in outer diameter to the side-branch balloon 406 and positioned to provide a passageway into the distal end 306 of side-branch member 106. The lumen of the deployment tube 906 may accommodate other deployment elements for deploying the prosthetic conduit 102, such as guidewires, balloon devices, snares, or other selected devices or materials. The deployment tube 906 may comprise, for example, a guiding catheter and may have specific bends incorporated into its distal end to facilitate the deployment of the side-branch member 106. Any suitable embodiment of a deployment tube may be utilized. During installation, once the side-branch balloon catheter 406 is inserted into the distal end 306 of side-branch member 106, the deployment tube 906 may be removed or may be used as a support to stiffen and/or guide the side-branch balloon catheter 406, thus aiding in the deployment of the side-branch member 106. Thus, installation techniques and devices may be selected according to the particular configuration, application, or situation.

Another embodiment of a delivery and deployment system according to various aspects of the present may be adapted to function with one or more self-expanding stents. For example, referring to Figures 9 and 10, the delivery system may include a push tube

900 and a constraining sheath 902 configured for maintaining the prosthetic conduit 102 in a compact configuration until delivery and deployment and delivering the prosthetic conduit 102 into the main vessel 108. Any suitable embodiment of a constraining sheath or structure to maintain the prosthetic conduit 102 in a compact configuration may be utilized.

5 The prosthetic conduit 102 and push tube 900 may be positioned within the constraining sheath 902 such that the proximal end 412 of the main member 104 is in contact with the distal end of the push tube 900. The constraining sheath 902 suitably contains the prosthetic conduit 102 and the push tube 900, and may be introduced into a 10 vessel or other bodily conduit, for example as a catheter may be introduced, and may be advanced to a desired position within a vessel. When the prosthetic conduit 102 is advanced to a desired location, the constraining sheath 902 may be pulled back proximally, the push tube 900 may be pushed distally, or both, to release the prosthetic 15 conduit 102 from the constraining sheath 902. Because the main member 104 may be self-expanding, once released from constraining sheath 902, the main member 104 may expand to contact the inner wall of main organism vessel 108.

The constraining sheath 902 may suitably include an aperture for allowing the side-branch guidewire 410 to protrude through the constraining sheath 902, which allows the side-branch guidewire 410 to help align the side opening 204 with the origin of the 20 side-branch vessel 110. The side-branch guidewire 410 may be extended laterally from the constraining sheath 902 and into the side-branch vessel 110 to facilitate the correct positioning of the prosthetic conduit 102. When the prosthetic conduit 102 is correctly positioned, the side-branch guidewire 410 may be retracted, allowing the constraining sheath 902 to be moved axially with respect to the prosthetic conduit 102.

25 The constraining sheath 902 may be configured to the particular application and environment. For example, referring to Figures 11 and 12, the constraining sheath 902 may include a distal tip 904, configured to enhance navigability of the constraining sheath 902 within bodily conduits. The distal tip 904 may be configured to have a tapered profile that reduces resistance during movement within bodily conduits and may suitably 30 include multiple wedge-shaped segments 1100. The tapered profile and wedge-shaped segments 1100 may enhance navigability within bodily conduits by providing a more hydro-dynamic distal tip 904 for the constraining sheath 902. The distal tip 904 may also be configured as a substantially closed structure to inhibit bodily fluids from entering the

constraining sheath 902. Furthermore, the wedge-shaped segments 1100 may be configured to be flexible, allowing the constraining sheath 902 to be easily moved relative to the prosthetic conduit 102.

5 The push tube may be configured in any suitable manner to facilitate delivery of the prosthetic conduit 102. For example, referring to Figure 13, an exemplary embodiment of a push tube 900 configured to deliver the prosthetic conduit 102 with the self-expanding main member 104 within an organism vessel may include a cross-section shaped as an incomplete annulus with a gap 1300. The push tube 900 with the gap 1300 may be configured to enable the push tube 900 to be easily removed from the organism 10 vessel after deployment of the prosthetic conduit 102 without removing or otherwise disturbing the side-branch balloon catheter 406 or the side-branch guidewire 410.

15 The push tube 900 may also include a section that extends within the lumen of the main member 104, providing additional stiffness during installation. The push tube 900 may also include a section extending along the entire length of the main member 104, and abutting the distal end 402 of the main member 104, which tends to offer further control during installation of the prosthetic conduit 102.

20 The side-branch member 106 may be pushed or pulled out of the interior of the main member 104 in any suitable manner, for example by pushing it out with the releasably attachable side-branch balloon catheter 406. Thus, in this embodiment, the main member 104 is self-expanding while the side-branch member 106 is balloon expandable. Any suitable deployment system, however, may be used to extend the side-branch member 106 from within the main member 104.

25 The prosthetic conduit 102 according to various aspects of the present invention may be manufactured from many different materials or combinations of materials and may be constructed by any suitable method. A prosthetic conduit 102 according to various aspects of the present invention, however, is formed using material that may be circumferentially distended with minimal foreshortening and recoil. Accordingly, the material(s) for the prosthetic conduit 102 may be treated to facilitate such distention characteristics.

30 For example, referring to Figure 14A-B, the main member 104 may be constructed by initially forming a film-tube (step 1410) of a thin, flexible material, such as a microporous polyethylene film, for example a segment of Solupor® 7P03A

microporous polyethylene film manufactured by DSM Solutech. In the present embodiment, the film has a nominal thickness of about 50 μ , a nominal porosity of about 85%, and a nominal weight per surface area of 7 g/m², though any of these characteristics may vary according to the particular application. Various alternative film-tubes may be employed. For example, films of any suitable material, both porous and non-porous may be used. The diameter and wall thickness of the graft component of main member 104 may be constant or may vary to create graft components with different properties and different geometries, such as but not limited to tapers and the like.

To form the main film-tube, the film is cut to a selected size, such as an approximately 230 x 155mm rectangular piece, and wrapped around the circumference of a mandrel, suitably comprising stainless steel, and having a desired diameter, such as about 16mm, to form a film-tube. Various tooling (mandrels, rods, etc) may be used. The tooling onto which the film is applied may be of a constant outer diameter, or may have a variable outer diameter to create tubes of various geometries such as tapers and the like. Any suitable tooling having any suitable shape may be employed.

In the present embodiment, the tube is wrapped in a direction perpendicular to the major axis of the tube. The film may be wrapped in any suitable manner, for example, helically with respect to the major axis of the tube, or in any other appropriate manner. The wrapping is completed with the 230mm long edges of the rectangular piece parallel to the major axis of the mandrel such that a desired thickness is achieved. In the present embodiment, approximately three layers of the film cover the mandrel. The circumference of the 16mm mandrel is approximately 50.3mm, so to achieve a film thickness of approximately three layers after wrapping, one side of the rectangular piece is cut to a dimension of about 155mm, providing a selected overlap length, such as approximately 4mm. During wrapping, the film may be treated, such as wet with isopropyl alcohol, to enable the film to better lay smoothly.

With the wrapping complete, both ends of the wrapped film section are secured to the mandrel, such as with wire. Next, the polyethylene film may be secured along its length to the mandrel. For example, the polyethylene section may be helically wrapped with porous polytetrafluoroethylene film, suitably covering the film-tube entirely, ensuring that the layers of the polyethylene film contact each other.

The layers of the wrapped film are bonded together to form a single tube (step 1412). Bonding of the layers may be achieved by any suitable method. For example, the 16mm mandrel may be placed in an air convection oven set at 150 °C for 10 minutes and subsequently removed and allowed to cool. Once cool, the helically wrapped porous

5 PTFE film as well as the securing wire are removed and discarded. The resulting 16mm inner diameter polyethylene tube is then removed from the 16mm outer diameter mandrel. The 150°C temperature and 10 minute time combination is chosen to bond the film layers to each other, forming a robust tube, but leaving the porous nature of the polyethylene film substantially unchanged, and avoiding thermal degradation of the film.

10 Any suitable temperature and time combination, however, may be used. Alternatively, heated dies that contact the film either partially or wholly may also be used. Further, various adhesives or coatings may be applied to the film to effect bonding. The use of such adhesives or coatings may result in tubes that are composite in nature, having the combined characteristics of the adhesive or coating as well as the characteristics of the

15 film material.

The film-tube may then be cut, if desired, to a particular length, such as approximately 70mm. The side opening 204 may then be formed in the tube, such as using a 4mm diameter biopsy punch (step 1414). Any suitable geometry and tooling may be employed to create the side opening 204. Additionally, alternative embodiments of the

20 side opening 204 may include sections of material protruding laterally from the main member 104, to which the side-branch member 106 may be attached.

The side-branch member 106, such as an approximately 4mm inner diameter polyethylene film-tube, may be formed in the same manner as the approximately 16mm inner diameter polyethylene film-tube described above (step 1416). In particular, a graft

25 material, such as 7P03A microporous polyethylene film, is cut to a selected size and shape, such as an approximately 230 x 42mm rectangle, and wrapped around the circumference of a mandrel having the desired outer diameter, such as about 4mm. In this instance, the circumference of the 4mm mandrel is approximately 12.6mm, so to achieve a film thickness of three layers after wrapping, one side of the rectangular piece is

30 cut to a dimension of 42mm, providing approximately 4mm extra film length for overlap. During wrapping, the film may be wet with isopropyl alcohol to facilitate smooth layers.

With the wrapping complete, both ends of the 230mm long wrapped film section may be secured to the mandrel, for example with wire. Next, the film is secured in

position, such as by helically wrapping a porous PTFE film over the 230mm long wrapped film section, covering the section substantially entirely. The PTFE film tends to secure the polyethylene film about the mandrel so that the layers of the polyethylene film contact each other.

5 The layers of the side-branch tube are then suitably bonded together to form the side-branch tube (step 1418). For example, the 4mm mandrel may be placed in an air convection oven set at 150 °C for 5 minutes and subsequently removed and allowed to cool. Once cool, the helically wrapped porous polytetrafluoroethylene film as well as the securing wire are suitably removed and discarded. The temperature and duration may be
10 selected according to any suitable criteria to bond the film layers to each other and form a robust tube, but substantially maintaining the porous nature of the polyethylene film and avoiding any significant thermal degradation or weakening of the film. The resulting 4mm inner diameter polyethylene tube is then removed from the 4mm outer diameter mandrel and suitably cut to a desired size, such as into two equal lengths.

15 In accordance with various aspects of the present invention, the side-branch tube and/or the main member 104 may be treated in any suitable manner to provide selected characteristics, such as circumferential distention and/or extension capabilities. In the present embodiment, the side-branch tube is treated to facilitate distention of at least a portion of the side-branch tube with relatively low foreshortening and/or recoil. The side-
20 branch tube is also treated to facilitate kink resistance.

For example, the side-branch tube may be processed with cycles of heat, stretching, and/or compressing. The side-branch tube may be heated and stretched to a desired length and/or diameter. In the present embodiment, the side-branch tube may be initially marked at a known interval (step 1420), such as two marks at a 70mm interval centered along the length of the side-branch tube. The film-tube is then secured to a mechanism configured to stretch the side-branch tube. Any suitable stretching apparatus may be used, and may include any suitable mechanism for securing the tube, stretching the tube, heating the tube, measuring, and/or controlling the amount and rate of stretching. For example, a sliding mandrel mechanism may comprise two lengths of
25 3mm outer diameter stainless steel tubing and a length of 1.6mm outer diameter stainless steel rod. One end of the rod is bent and inserted into one of the 3mm outer diameter tubing lengths such that it is substantially immobile. Both lengths of the 3mm outer diameter tubing have a 360° groove cut into the wall approximately 3mm away from one
30 20

end. The film-tube is fitted coaxially over the 1.6mm rod and attached to the 3mm outer diameter tubing by manually tying a wire over the film-tube and into the groove at the end of the 3mm outer diameter tubing. The other length of 3mm outer diameter tubing is then fitted coaxially over the 1.6mm rod and the same manual wire tying process is used 5 to secure the other end of the film-tube to the 3mm outer diameter tubing.

When the side-branch tube is secured to the sliding mandrel mechanism, the assembly is exposed to heat (step 1422), such as via an air convection oven set at a selected temperature, such as 150 °C. The oven is configured with holes at each end so that the sliding mandrel mechanism and the attached film-tube can be inserted such that 10 the film-tube is approximately centered within the oven chamber and each of the 3mm outer diameter tubing lengths extend out of each end of the oven. The side-branch tube is heated for a selected duration, such as one minute, and then slowly stretched by manually pulling the ends of the 3mm outer diameter tubing lengths extending out of each end of the oven (step 1424). The film-tube is stretched in this manner to a desired length and/or 15 diameter. Other parameters, such as the tensile force experienced by the tube, or the outer diameter of the tube during stretching may also be monitored and/or controlled.

In the present embodiment, the side-branch tube is stretched until the marks are approximately 130mm apart. The lengthening causes the film-tube to reduce in diameter such that it substantially contacts the 1.6mm rod. Tension is maintained on the film-tube, 20 now stretched and reduced in diameter, ensuring that no significant change in length occurs while the sliding mandrel mechanism is removed from the oven. The film-tube is next allowed to cool and subsequently removed from the sliding mandrel mechanism.

At this point, the side-branch tube may be circumferentially distended. The side-branch tube may be further processed, however, to achieve additional characteristics. For 25 example, the side-branch tube may be distended to facilitate later distention with reduced force up to a selected limit. For example, the side-branch tube may be initially distended to a first selected diameter (step 1426), such as by manually fitting the tube over a tapered stainless steel mandrel having a 2mm outer diameter section approximately 200mm in length, and tapering up to an outer diameter of 3.8mm over a length of approximately 30 40mm. When fitted entirely over the 3.8mm outer diameter section of the mandrel and pulled taut, a distance of approximately 81mm separates the two pen marks on the film-tube. Next, the tube is removed from the 3.8mm tapered mandrel, and then further distended over a 4mm tapered mandrel (step 1428). When fitted entirely over the 4mm

outer diameter section of the mandrel and pulled taut, a distance of approximately 75mm separates the two pen marks on the film-tube. In the present embodiment, the distention is completed in two steps to make the process easier, though the distention may be performed in greater or fewer steps.

5 Varying amounts of distention may be performed to achieve varying final distensibility characteristics. The film-tube may be distended anywhere from zero to near the circumference at which it breaks, and the distention may be accomplished in any number of steps. The distention of the exemplary film-tube is suitably performed at ambient temperature conditions, however, may be

10 employed during the distention. The use of elevated temperature may be required for film-tubes of different materials, or for film-tubes of greater thickness. Moreover, any suitable mechanism and method may be employed to complete the distention. For example, as an alternative to the use of tapered mandrels, a balloon or bladder may be utilized to pressurize the film-tube and cause distention.

15 The side-branch tube may be further processed, such as to add features like flexibility and/or kink resistance. In the present embodiment, the side-branch tube is processed for kink resistance by sequentially stretching the tube to achieve a desired diameter and compressing the side-branch tube to form small corrugations. The corrugations may be formed in any suitable manner, and facilitate bending of the side-branch member 106 without kinks.

20 For example, the side-branch tube may be initially stretched (step 1430) using any suitable mechanism, such as a linear slide with a manually driven lead screw. Each end of the side-branch tube is secured onto the linear slide mechanism, for example using clamps. Heated air, such as from a hair drying gun set on low, may be applied to warm the side-branch tube and soften the graft material. Turning a hand crank connected to a lead screw actuates the linear slide. The film-tube may thus be slowly stretched. Periodically, the stretching of the film-tube may be halted, allowing the stress within the tube to diminish, thereby avoiding breaking of the tube. The film-tube is stretched until a desired distance, such as approximately 144 mm, separates the two marks on the side-branch tube. The film-tube may also be stretched until a desired diameter is achieved. The side-branch tube may then be allowed to cool and/or relieve stress for a selected time and temperature, such as at least five minutes at ambient temperature. The tube is then removed from the linear slide mechanism. The processes of distending the tube and

subsequently stretching it to reduce its diameter may be repeated any number of times if desired.

The side-branch tube may also be processed to provide other characteristics, such as resistance to kinking and/or foreshortening. For example, to add kink resistance and 5 reduce foreshortening upon distention, the side-branch tube may be processed to form corrugations. For example, the side-branch tube may be fitted coaxially over a 1.2mm diameter stainless steel rod and again marked for reference (step 1432). The marks are separated by a selected interval, such as 50mm, and the marks may be centered along the length of the side-branch tube. The side-branch tube is also suitably constrained against 10 the rod, for example using a thin, strong, porous PTFE film helically wrapped over the side-branch tube.

The overwrapped side-branch tube on the 1.2mm diameter rod may then be compressed. To facilitate compression, the side-branch tube is suitably heated (step 1434), such as in an air convection oven set at a selected temperature and duration, such 15 as 70 °C for at least about 10 minutes. The side-branch tube may then be removed from the oven and compressed longitudinally (step 1436), tending to cause a reduction in length. The PTFE film overwrap tends to inhibit formation of gross corrugations along the surface of the film-tube during compression. Any suitable method may be used to control the size of the corrugations formed along the surface of the film-tube. For 20 example, the film-tube while on the 1.2mm diameter rod may be placed within a tube having an inner diameter slightly larger than the outer diameter of the film-tube prior to being overwrapped, and may then be longitudinally compressed within the tube.

The film-tube is longitudinally compressed a desired amount, for example so that a distance of approximately 28.5mm separates the two pen marks originally separated by 25 a distance of 50mm. The side-branch tube may then cool to ambient temperature, the polytetrafluoroethylene film overwrap is removed, and the film-tube is removed from the 1.2mm diameter rod. The resulting 1.2mm inner diameter polyethylene film-tube may then be gently pulled (step 1438) or otherwise smoothed to remove any inconsistently large corrugations, leaving a substantially uniform tube surface.

30 The longitudinal compression tends to impart corrugations along the surface of the film-tube or otherwise shorten the film-tube. In some materials, like polyethylene, the compression may cause the tube surface to exhibit small corrugations or wrinkles. For

other materials, the compression may cause compression of the material itself, such that the material condenses without forming corrugations in the surface. The porosity of the material and the temperature may also affect the formation of corrugations or other shortening of the film-tube. The wrinkles or other compression serve to enhance the

5 flexibility of the tube, tending to allow the tube to undergo substantial bending without kinking, and also serve to inhibit any change in length of the film-tube during distention. The processes for achieving the various characteristics, including kink resistance and foreshortening minimization, may be applied to other materials as well, such as material treated in accordance with the disclosure of U.S. Patent No. 5,800,522, issued September 10 1, 1998, to Campbell, et al. Moreover, other methods may be applied to form corrugations or compress the tube, such as tying thin wires spaced at regular intervals around the circumference of the film-tube while the tube is on the 1.2mm diameter rod. With the wires in place, the tube may be longitudinally compressed. The presence of the wires during the compression results in the formation of wrinkles of a pre-determined 15 size.

Although the graft component 310 described above is circumferentially distensible with low recoil and foreshortening, the use of non-distensible tubes as the graft component is possible. The graft component, distensible or not, may be of any suitable material known in the prior art, or any suitable material that may become 20 available in the future. Additionally, graft component 310, may be constructed from any suitable form or combination of forms such as but not limited to extruded tubing, braided tubing, textile tubing, and as discussed tubing created from films or membranes. The graft component may be processed by any suitable methods. The wall thickness of the graft component 310 of the side-branch member 106 may be constant or may vary to 25 create graft components with different properties. For example a graft component may have a thinner wall at the distal end, and a thicker wall at the proximal end, or vice versa. The graft component may further have any suitable degree of porosity. Further, all of the techniques and materials may be applied to other components of the prosthetic conduit 102, such as the main member 104, or other devices and materials.

30 In an alternative embodiment, a graft component may be created from a woven textile tube. Woven textile tubes, such as braided tubes formed generally of helically wound strands, may be constructed from various suitable materials, such as but not limited to polyester, polypropylene, and polytetrafluoroethylene. Braided tubes may

exhibit distensible behavior. Typically, distention of braided tubes is accompanied by pronounced foreshortening. The relationship between the amount of distention and the amount of foreshortening can be varied according to the parameters utilized in the manufacture of the tube.

5 A braided tube according to various aspects of the present invention is circumferentially distensible. A braided tube may be initially elongated in the direction of the major axis until the ensuing reduction in diameter is complete. Next, the tube may be cut to a selected length and fitted coaxially over a rod or mandrel of appropriate outer diameter. The ends of the tube are then secured to the rod or mandrel using wire, and the 10 elongated braided tube is then overwrapped with porous polytetrafluoroethylene film and longitudinally compressed. The tube, prior to or during the longitudinal compression, may be heated.

The porous polytetrafluoroethylene film tends to control the size of corrugations along the surface of the tube. Next, for example, the tube is suitably placed in an oven 15 and heated. The time and temperature parameters are suitably chosen such that the tube, after removal from the mandrel, substantially maintains the longitudinally compressed length, but the strands that form the tube are not permanently bonded to each other. In this fashion, the tube may be distended, but having been longitudinally compressed, foreshortens minimally. The braided tube may be gently pulled to remove any 20 inconsistently large corrugations that may have been formed during the longitudinal compression process.

Any suitable degree of longitudinal compression may be performed to the braided tube. For example, in one embodiment two marks separated by a known distance may be placed on the braided tube prior to the tube being elongated, and the marks may be 25 returned to their original spacing during the longitudinal compression process. Any suitable method may be employed to maintain the tube in its longitudinally compressed state but still allow distention. For example, a mild adhesive may be applied to the surface of the tube either partially or wholly. Alternatively, heated dies that contact the surface of the tube either partially or wholly may be used.

30 In accordance with various aspects of the present invention, the side-branch tube may be equipped with a support (step 1440), such as the side-branch stent 112 at the distal end of the side-branch member 106. The stent may be added to the side-branch

tube in any appropriate manner. For example, one end of the 1.2mm inner diameter polyethylene graft component may be slightly flared, such as by using a pair of small hemostats. The graft component may then be fitted coaxially onto a 1.2mm diameter stainless steel rod and constrained against the rod, for example using a helical overwrap 5 of thin, strong, porous PTFE film. The overwrapping suitably begins on the rod adjacent to the non-flared end of the graft component and ends at the base of the small flare at the end of the graft. The flared end of the graft may then be everted, for example manually using small hemostats. The PTFE overwrap film may be removed as necessary as the graft is everted until an everted section of a desired length, such as approximately 22mm 10 long, is obtained.

The stent may then be placed within the folded over portion of the graft. For example, a 0.64mm diameter wire is suitably pushed underneath the everted section of the graft component, slightly distending the everted section, creating a small annular space between the everted section and the underlying graft component. A selected stent, such 15 as an 18mm long balloon-expandable side-branch stent 112, is then placed within the annular space between the everted section and the underlying graft component, the end of the side-branch stent 112 abutting the fold at the end of the everted section of the graft component.

The approximately 4mm long length of everted graft component extending 20 beyond the stent is then suitably bonded to the underlying graft component, for example using a conventional soldering iron, to maintain the position of the side-branch stent 112. The bonding process suitably controls the application of heat to ensure that the graft component is not overly heated, substantially changing the graft properties, or damaged during the bonding process. At this point, the everted section of graft component over the 25 side-branch stent 112 may be radially compressed, reducing the outer diameter of the end of the graft component encompassing the stent. The remaining PTFE overwrap film may be removed and the graft component and stent are suitably removed from the 1.2mm diameter rod.

Alternative embodiments of the side-branch tube may omit the side-branch stent 30 112 or replace it, for example with another type of stent. For example, the side-branch stent 112 may be a self-expanding stent. A suitable self-expanding stent may be placed within the annular space created between the everted section and the underlying film-tube as described. In such an embodiment the self-expanding stent may be maintained in a

compact configuration by the graft component covering it, and thus the combination of the self-expanding stent and the graft component is functionally balloon expandable. One or more stents may be used at any location along the graft component. In some embodiments the use of both balloon expandable and self-expanding stents may be 5 preferred. Further, any suitable method may be employed to attach or incorporate stents to the graft component. For example stents may sutured to the graft component, or may be attached by an adhesive. In some embodiments it may be possible to bond the stent to the graft component using heat.

In an exemplary embodiment according to various aspects of the present 10 invention, an attachment area for attaching the main member 104 to the side-branch member 106 is provided (step 1442). For example, the side-branch member 106 suitably includes the conical section 302 and/or the flange 304. The conical section 302 may be formed in or attached to the side-branch member 106 in any suitable manner. For example, the portion of the graft component from the bond site 404 to the proximal end 15 308 is initially distended by coaxially fitting it over a 2mm diameter steel rod, suitably such that the graft component does not compress longitudinally and become grossly corrugated, or substantially elongate. Once distended, the graft component and incorporated stent are suitably removed from the 2mm diameter rod. In the present embodiment, the length of the graft component from the bond site 404 to the proximal 20 end 308 is approximately 50mm.

To form the conical section 302 and flange 304, the graft component, starting at the proximal end 308, is distended in a conical configuration, such as by fitting it over a 25 4mm tapered mandrel. The tapered mandrel increases from an outer diameter of approximately 1.3mm to an outer diameter of 4mm over a length of approximately 30mm. In the present embodiment, the graft component is fitted over the 4mm tapered mandrel such that the proximal end extends approximately 6mm onto the 4mm outer diameter section of the mandrel.

Thus, in this particular embodiment, distending the proximal end 308 over a 30 tapered or conically shaped mandrel at ambient temperature forms the conical section 302 of the side-branch member. The conical section may have any suitable geometry, provided that the proximal end of the side-branch member is able to be attached to the side opening 204 of the main member 104. Additionally, the conical section may be formed by any suitable method at any suitable temperature, such as for example

distention via a balloon, or the use of any other tube flaring equipment. The method and temperature employed are dependent on the embodiment of the graft component. In an alternative embodiment, the conical section may be a separate piece, attached to the side-branch member by any suitable method.

5 Similarly, the flange may be formed in or attached to the side-branch member 106 in any suitable manner. For example, while side-branch member 106 remains situated on the 4mm tapered mandrel, four cuts may be made at the proximal end of the graft component, for example using a razor blade. The cuts are suitably substantially parallel to the major axis of the graft component, extending approximately 3mm from the
10 proximal end of the graft component at selected intervals, such as 0, 90, 180, and 270° around the circumference of the proximal end 308 of the graft component. The four 3mm long cuts form four substantially equal sections around the circumference of the proximal end 308 of the graft component. The four sections may then be bent to a position extending laterally, perpendicular to the major axis of the graft component, to form the
15 flange 304. With the embodiment of the conical section 302 formed via the 4mm tapered mandrel, and the embodiment of the flange created by the four equal sections around the circumference of the proximal end of the graft component, the graft component may then be removed from the 4mm tapered mandrel.

20 The flange 304 may be of any suitable geometry to facilitate and/or strengthen the connection of the side-branch member to the main member. The flange 304 may be formed by any suitable mechanism, such as, but not limited to, flaring the proximal end 308 of the side-branch member 106 and then inverting the flared section, or using any other suitable tube flanging equipment or process. Alternatively, the flange 304 may be a separate piece, attached to the side-branch member 106 by any suitable method, or
25 attached to the side opening 204, or formed from the material surrounding the side opening 204. Any adaptation of the proximal end 308 of the side-branch member 106, or the side opening 204 in the main member 104, either alone or in combination, may be utilized.

30 The main member 104 and side-branch member 106 may be connected according to any suitable technique or process (step 1444). In the present embodiment, for example, the main member 104 is partially fitted coaxially onto a 16mm outer diameter mandrel, leaving the lumen of the main member 104 and the side opening 204 accessible. The side-branch member 106 may be inserted, distal end first, into the lumen of the main

member 104 and through the side opening 204 until the flange 304 abuts the inner surface of side opening 204.

When the flange 304 abuts the inner surface of the main member at the side opening 204, the flange 304 may be secured to the main member 104 in any suitable manner. For example, the main member 104 may be advanced down the length of the 16mm outer diameter mandrel, trapping the four equal sections comprising the flange 304 between the mandrel and the main member 104. The main member 104 and the side-branch member 106, via flange 304, are then bonded together, for example thermally, at the side opening 204, such as via a soldering iron. The bonding, however, may be performed using any suitable mechanism or techniques, such as, but not limited to, sutures or adhesives.

The prosthetic conduit 102 may be configured in any suitable manner for delivery. In the present embodiment, the side-branch member 106 and the main member 104 are connected and placed in a compact configuration for delivery, for example with the side-branch member 106 inside of the main member 104. A delivery and/or a deployment system, either wholly or in part, may also be added to the assembled prosthetic conduit 102.

The prosthetic conduit 102 may be configured for delivery and deployment in any appropriate manner. For example, the side-branch member 106 may be disposed inside the main member 104 to facilitate placement (step 1446). In the present embodiment, a 1.2mm diameter stainless steel rod is inserted coaxially within the side-branch member 106. To enable eversion of the side-branch member 106, the side-branch member is suitably constrained from dilation or longitudinal compression, such as by helically overwrapping the side-branch member 106 to the rod using porous 25 polytetrafluoroethylene film. The overwrap suitably begins on the 1.2mm diameter rod adjacent to the distal end 306 of the side-branch member 106 and ends adjacent to the proximal end 308 of the side-branch member 106. In the present embodiment, since all regions of the side-branch member 106 with exception to the region encompassing side-branch stent 112 have an inner diameter larger than 1.2mm, care is taken during the 30 application of the overwrap film, creating lengthwise folds and avoiding twisting of the side-branch member 106. Alternatively, to enable folding, the side-branch member 106 may be covered with an elastomeric tube of appropriate inner diameter and thickness.

The 1.2mm diameter rod is then suitably used to push the side-branch member 106 into the lumen of the main member 104, causing the side-branch member to evert onto itself until a desired portion, such as the entire length of side-branch member 106, resides within the lumen of the main member 104. During the eversion process, the 5 porous polytetrafluoroethylene film may be removed as necessary. Alternatively, if an elastomeric tube is used, the tube may be of sufficient length to evert over itself, leaving a free end extending beyond the distal end of the side-branch member 106. During the eversion of the side-branch member 106 into the main member 104, the elastomeric tube could be removed via eversion in the opposite direction. Once the side-branch member 10 106 is completely everted, the remaining overwrap film and the 1.2mm diameter rod may be removed.

In the illustrative embodiment, the side-branch balloon catheter 406 is positioned within the side-branch member after the eversion process is completed. In an alternative embodiment, a side-branch guidewire 410 may be positioned within the everted side- 15 branch member 106. In such an embodiment, the side-branch balloon catheter 406 may or may not be included within the side-branch member 106.

In another alternative embodiment, the side-branch balloon catheter 406 may be placed coaxially within the side-branch member 106, in lieu of the 1.2mm diameter rod. The side-branch balloon catheter 406 may be located at any suitable place along the 20 length of the side-branch member 106, such as at the distal end, suitably in registry with the side-branch stent 112. The side-branch balloon catheter 406 may then be releasably attached to the side-branch member 106. With the side-branch balloon catheter 406 releasably attached to the side-branch member 106, the side-branch balloon catheter 406 in cooperation with polytetrafluoroethylene film or any suitable mechanism may be used 25 to evert the side-branch member 106 within the main member 104. A side-branch guidewire 410 placed within the guidewire lumen of the side-branch balloon catheter 406 may also be included.

In yet another alternative embodiment, a guiding catheter, or a deployment tube similar to a guiding catheter, may be placed coaxially within the side-branch member 106 30 in lieu of the 1.2mm diameter rod. If the side-branch member 106 is equipped with the side-branch stent 112, the guiding catheter or tube may be positioned such that its distal end abuts the proximal end of the side-branch stent 112. When so positioned, the side-branch stent 112 may be configured with an inner diameter approximately equal to that of

the guiding catheter or deployment tube. In such an arrangement, the guiding catheter or deployment tube may provide a well-defined passageway for other devices and may aid in the extension of the side-branch member 106. Alternatively, with the guiding catheter or deployment tube positioned as described, the distal end may be releasably attached to 5 the graft component, for example by an adhesive, thermal bond, or other suitable method.

Regardless of how the guiding catheter or tube is positioned within the side-branch member 106, once it is in the desired location, the process of evertting the side-branch member into the main member may be completed by using the guiding catheter or tube in cooperation with polytetrafluoroethylene film or any suitable mechanism. If 10 additional support is required during eversion, a rod for example may be placed within the guiding catheter or tube. Once the eversion process is completed, other devices may be placed within the guiding catheter or tube or within the side-branch member 106.

The prosthetic conduit 102 may further be equipped with additional delivery system and/or deployment system components, or may otherwise be prepared for delivery 15 and deployment. For example, the side-branch balloon catheter 406 may be inserted coaxially within the distal end of the side-branch member 106 and releasably attached to the side-branch member 106. Further, the prosthetic conduit 102 may receive the main balloon catheter 400 or be placed within a constraining sheath 902. For example, the prosthetic conduit 102 may be suitably folded into a compact configuration and placed in 20 a constraining sheath 902. The push tube 900 may then be placed within the constraining sheath 902. If required, the side-branch balloon 406 may be removed during the folding process, and repositioned when convenient. Any suitable arrangement of a constraining sheath 902, push tube 900, side-branch balloon 406, and other components may be employed. In some embodiments, particularly if the push tube 900 is adapted to extend 25 within the main member 104, the prosthetic conduit 102 and the push tube 900 may be arranged prior to placement within the constraining sheath 902.

The various embodiments of the present invention may be delivered and installed by any known method, using any combination of devices. For example, the delivery system may comprise any combination of suitable introducer sheaths, guidewires, balloon 30 catheters, guiding catheters, deployment tubes, constraining sleeves, push tubes, and/or any other accessory in any suitable arrangement.

Example

To demonstrate the characteristics of a preferred embodiment of a circumferentially distensible tube, a 1.2mm inner diameter film-tube was created using essentially the same process as described above. A 230 x 45mm rectangular piece was cut from Solupor 7P03A microporous polyethylene film and wrapped around the

5 circumference of a 4mm outer diameter stainless steel mandrel. With the wrapping complete, both ends of the 230mm long wrapped film section were secured to the mandrel with wire. Porous polytetrafluoroethylene film was helically wrapped over the 230mm long wrapped film section, covering the section entirely. The 4mm mandrel was then placed in an air convection oven set at 143 °C for 7.5 minutes and subsequently
10 removed and allowed to cool. Once cool, the helically wrapped porous polytetrafluoroethylene film as well as the securing wire were removed and discarded. The resulting 4mm inner diameter polyethylene tube was then removed from the 4mm outer diameter mandrel and cut into two equal lengths.

Next, pen marks were placed on one of the 4mm inner diameter film-tubes, and
15 the film-tube was secured to a sliding mandrel mechanism. In this instance, the sliding mandrel mechanism had a 1.1mm diameter rod. The entire assembly was heated in an air convection oven set at 150 °C for one minute, and the film-tube was then carefully stretched until the interval between the two pen marks (originally spaced at 70mm) was approximately 141mm. The stretching caused the film-tube to reduce in diameter,
20 substantially contacting the 1.1mm rod. The film-tube was then allowed to cool and removed from the sliding mandrel mechanism.

The film-tube was then manually distended over 3.8 and 4mm outer diameter tapered mandrels. The approximate lengths separating the two pen marks on the film-tube while on the 3.8 and 4mm outer diameter tapered mandrels were 85 and 80mm
25 respectively. With the distention completed, and the film-tube removed from the 4mm tapered mandrel, the film-tube was secured to the linear slide and stretched until the distance between the two pen marks was approximately 154mm. With the stretching complete, the film-tube was allowed to remain clamped within the linear slide mechanism for at least of 5 minutes at ambient temperature.

30 The film-tube was then manually fitted coaxially over a 1.2mm diameter stainless steel rod. The processing of the film-tube was then completed following the steps as previously described. As previously discussed, the small corrugations were formed within the finished tube, tending to allow the tube to be bent without kinking.

Additionally, the completed film-tube was readily circumferentially distensible without significant length change (foreshortening) and without significant diameter change post distention (recoil). The 1.2mm inner diameter film-tube was capable of circumferential distention to an inner diameter of approximately 4mm.

5 To provide comparative data, a nondistensible film-tube was created. The nondistensible film-tube was made with approximately the same number of film layers and the same film used to make the 1.2mm circumferentially distensible film-tube above, but was not processed to render it circumferentially distensible or to exhibit enhanced flexibility.

10 More particularly, a 200 x 17mm rectangular piece of Solupor 7P03A microporous polyethylene film was cut and wrapped around the circumference of a 1.5mm diameter stainless steel rod. In this case, the circumference of the 1.5mm rod was approximately 4.7mm, so to achieve an approximate film thickness of three layers after wrapping, one side of the rectangular piece was cut to a dimension of 17mm, providing approximately 3mm extra film length for overlap. With the wrapping complete, both ends of the 200mm long wrapped film section were secured to the rod with wire and the section was helically wrapped with porous polytetrafluoroethylene film. The 1.5mm rod was then placed in an air convection oven set at 143 °C for 3 minutes and subsequently removed and allowed to cool. Once cool, the helically wrapped porous

15 polytetrafluoroethylene film as well as the securing wire were removed and discarded. The 1.5mm inner diameter polyethylene tube was then removed from the 1.5mm diameter rod. The 1.5mm inner diameter polyethylene film-tube did not possess any significant circumferential distensibility, nor did it possess any enhanced flexibility. If desired, however, enhanced flexibility may be imparted to such non-distensible tubes by following

20 process steps similar to those previously described for helically wrapping, warming, and longitudinal compression.

The distensibility characteristics for the distensible and the non-distensible tube were measured for comparison. A 16.5mm long section was cut from the 1.2mm inner diameter circumferentially distensible film-tube. The section was distended slightly by fitting it coaxially over a 1.5mm diameter rod. The 16.5mm long section of tube was then coaxially fitted over an angioplasty balloon with a nominal length of 15mm, and a nominal diameter of 4mm. The distention of the tube to a 1.5mm inner diameter was required so that the tube could be easily placed onto the uninflated balloon without any

change in length. Also, a length of 16.5mm was utilized so as to cover the entire working length of the balloon such that the balloon edges (shoulders) did not inflate at a faster rate than the center. Inflation of the shoulders at a faster rate than the balloon center causes the shoulders at each end of the balloon to bulge and longitudinally compress the length

5 of tube. Such longitudinal compression not only changes the length, but also changes the distensibility characteristics of the tube. This adverse interaction is caused by a mismatch between the length of the balloon and the length of the tube being distended by the balloon. Thus, a length of 16.5mm successfully matched the tube length to the balloon length and avoided such adverse interactions.

10 With the tube fitted coaxially onto and centered along the length of the uninflated balloon, digital calipers were used to measure the outer diameter of the tube. The balloon was then inflated at ambient temperature using a hand-held inflation device in approximately 0.1MPa (1atm) increments and the outer diameter of the tube was measured at each increment until a pressure of 1.6MPa (16atm) was achieved. Once the

15 1.6MPa inflation pressure was achieved and the final outer diameter measurement was completed, the balloon was deflated and the length of the tube was measured again using digital calipers.

The difference between the length of the tube prior to distention and the length of the tube after distention is the amount of foreshortening undergone by the tube. The

20 balloon was carefully repacked into the protective packaging sleeve that was provided by the manufacturer and the same test procedure and data collection were repeated on the 1.5mm non-distensible tube. The recorded outer diameter data were used to create a plot (Figure 15) of tube outer diameter as a function of inflation pressure.

Figure 15 shows a plot of tube outer diameter as a function of inflation pressure for both the distensible and the non-distensible tube. The distensible tube generally increases in diameter with increasing inflation pressure. The diameter increase tends to reduce once the tube has reached outer diameters above approximately 3.75mm, signifying that the tube is approaching the maximum amount of distention that can be achieved without the application of extremely high inflation pressures. The distensible tube reaches an outer diameter of approximately 4mm under 1.6MPa (16atm) inflation pressure.

Figure 15 includes outer diameter data for the balloon catheter only. These data are provided within the instructions for use of the balloon catheter, and are included in Figure 15 to show that the outer diameter of the balloon catheter alone (as a function of inflation pressure) is greater than that of the distensible tube during distention by the balloon catheter. Thus, the distensible tube is limiting the outer diameter of the balloon catheter during inflation. Note that the data provided within the instructions for use of the balloon catheter range only from 0.2 to 1.6MPa (2 to 16atm). Figure 15 also shows the distensibility characteristics of the non-distensible tube. The diameter of the non-distensible tube remains fairly constant and is relatively unchanged by the inflation pressure imparted to it via the balloon catheter.

Prior to distention, as stated above, the length of the distensible tube was 16.5mm. The length of the distensible tube after distention was measured to be approximately 15.7mm, resulting in approximately 0.8mm of foreshortening. Dividing the 0.8mm foreshortening value by the 16.5mm length prior to distention, and converting to a percentage yields a foreshortening percentage of approximately 4.8 percent. Similarly, the length of the non-distensible tube after distention (although the tube did not actually undergo a substantial change in diameter) was measured to be 16.1mm, yielding a foreshortening value of 0.4mm or approximately 2.4 percent. In the case of the non-distensible tube, the change in length was apparently due primarily to the shoulders of the balloon bulging against the ends of the tube and causing the slight length reduction.

To determine the recoil characteristics of the distensible 1.2mm inner diameter tube, the tube was carefully fitted over a 1.5mm diameter rod, causing a 25% increase in diameter. The tube was then removed from the rod and left undisturbed for 30 minutes. After the passing of 30 minutes, the tube was pushed back onto the 1.5mm rod by carefully grasping one end of the tube and pushing the other end of the tube onto the rod. An approximately 6mm length of tube was pushed onto the 1.5mm diameter rod before the tube buckled and could be pushed onto the rod no further. Because the tube could be fitted onto the 1.5mm rod at least partially, there is indication of little to no recoil (or change in diameter).

The same tube is then studied for flexibility or kink resistance. The tube was carefully wrapped around the circumference of an 11mm outer diameter mandrel with no indication of gross buckling of the tube. The tube was then released from the mandrel, and rather than returning to its original substantially straight configuration, it remained

curved, in a semi-circular shape having a radius of approximately 15mm. To provide comparative data, a length of the 1.5mm non-distensible tube was wrapped around the circumference of the same 11mm outer diameter mandrel. The non-distensible tube exhibited various points where kinking (gross buckling) occurred. When released from 5 the mandrel, the non-distensible tube returned to a substantially straight configuration.

To further demonstrate the recoil characteristics of the distensible 1.2mm inner diameter tube, a new length of tube was tested, in a manner similar to that described above. In this case, rather than distending the tube 25%, a length of the tube was 10 distended over the 4mm tapered mandrel. The tube was then removed from the tapered mandrel and left undisturbed for 30 minutes. After 30 minutes, attempts were made to push the tube onto a 4mm (non-tapered) mandrel by carefully grasping the undistended end of the tube and pushing the distended end of the tube onto the mandrel. The tube, however, having undergone some recoil, did not fit onto the 4mm mandrel.

Similar attempts were then made to coaxially fit the tube onto a 3.8mm (non-tapered) mandrel. The section of the tube, which was distended to a 4mm inner diameter, fit over the 3.8mm mandrel easily, indicating that the inner diameter of the tube was then 15 approximately 3.8mm. Thus, the distended diameter of the tube was 4mm and the recoil diameter of the tube was approximately 3.8mm, resulting in a recoil value of approximately 0.2mm. Dividing the approximate recoil value of 0.2mm by the distended 20 diameter of 4mm, and converting to a percentage yields a percent recoil value of approximately 5 percent.

Accordingly, a prosthetic conduit according to various aspects of the present invention may be suitable for the treatment of both aneurysmal and occlusive vascular disease within coronary and peripheral blood vessels, as well as within the 25 neurovasculature, and various other bodily conduits. The prosthetic conduit facilitates endoluminally treating aneurysmal vessels while maintaining normal blood flow to a side-branch vessel originating along the length of the aneurysm. Thus, the prosthetic conduit tends to alleviate the potential for ischemic complications in other bodily locations, and also tends to inhibit the situation of retrograde blood flow through the side- 30 branch vessel, facilitating the aneurysm exclusion process. The prosthetic conduit also provides, by virtue of the graft material, a physical barrier that impedes re-proliferation of disease into the lumen of the treated blood vessel. Moreover, the prosthetic conduit provides a preformed bifurcated junction, obviating highly accurate placement as

required during the formation of a bifurcation using two stents. The prosthetic conduit including the main member and side-branch member grafts also tends to control redistribution of plaque at the side-branch and reduce the chance of inadvertent blockage due to plaque movement.

5 In accordance with various other aspects of the present invention, the prosthetic conduit provides several advantages and characteristics. For example, such a prosthetic conduit may allow relative ease of sizing, and may accommodate a range of main and side-branch vessel diameters. The prosthetic conduit may also offer a high degree of flexibility, bending substantially without kinking, and thus having the ability to conform
10 to a variety of bifurcation geometries. Additionally, the prosthetic conduit may be installed through a singular vascular access site. Also, the prosthetic conduit may include radiopaque markers, or may be at least partially constructed of materials that are easily visualized radiographically, facilitating the installation process. The prosthetic conduit may also be installed utilizing conventional, non-specialized tools and devices for
15 vascular surgery, interventional radiology, interventional cardiology, and the like.

The present invention has been described above with reference to various preferred embodiments. However, changes and modifications may be made to various exemplary embodiments without departing from the scope of the present invention. For example, various combinations of the main members 104 and one or more side-branch
20 members 106 may be provided. Further, various changes in the configurations of the main member 104 and the side-branch member 106, for example various combinations of stents and grafts and various materials, may be provided. These and other changes or modifications are intended to be included within the scope of the present invention as set forth in the appended claims.

Claims

1. A conduit, comprising:

a main member, comprising a wall having at least one opening defined in the wall;

and

5 at least one side-branch member connected to the main member;

wherein the at least one side-branch member is extendable through the at least one opening from within the main member.

2. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member comprises:

10 a graft material; and

a support supporting at least a portion of the graft material.

3. The conduit of claim 2, wherein the support comprises at least one of a stent, a barb, an adhesive, and a pin.

4. The conduit of claim 1, further comprising at least one balloon catheter releasably attached to at least one of the main member and the at least one side-branch member.

15 5. The conduit of claim 1, further comprising at least one of a balloon catheter, a guiding catheter, a guidewire, or a deployment tube disposed within at least one of the main member and the side-branch member.

20 6. The conduit of claim 1, further comprising a delivery system having at least one sheath configured to retain at least one of the main member and the at least one side-branch member.

7. The conduit of claim 1, further comprising a flange connected to the at least one side-branch member and to the wall of the main member around the opening.

25 8. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member is circumferentially distensible.

9. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member includes at least one of polytetrafluoroethylene, polyurethane, polyethylene, polyether sulfone, and polyester.

30 10. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member includes at least one of a film-tube, extruded tubing, braided tubing, and textile tubing.

11. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member is treated for at least one of elution of drugs, biocompatibility, radioactivity, and radiopacity.

12. The conduit of claim 1, wherein the at least one side-branch member is configured 5 to be extended through the opening by at least one of a balloon catheter, a snare, or a deployment tube.

13. The conduit of claim 1, wherein at least one of the main member and the at least one side-branch member is kink resistant.

14. The conduit of claim 1, wherein at least one of the main member and the at least 10 one side-branch member may be distended with at least one of minimal foreshortening and low recoil.

15. A conduit, comprising:

a main member, comprising:

a main member graft material defining a side opening; and

15 a main member stent supporting at least a portion of the main member graft material; and

a side-branch member disposed within the main member and configured to be extended through the side opening, comprising:

a side-branch member graft material, wherein side-branch member graft

20 material is connected to the main member graft material around the side opening; and a side-branch member stent supporting at least a portion of the side-branch member graft material.

16. The conduit of claim 15, further comprising at least one of a balloon catheter, a guiding catheter, a guidewire, or a deployment tube disposed within at least one of the 25 main member and the side-branch member.

17. The conduit of claim 15, wherein the proximal end of the side-branch member includes a flange connected to the main member graft material around the side opening.

18. The conduit of claim 15, wherein at least one of the main member and the side-branch member is circumferentially distensible with at least one of minimal 30 foreshortening and low recoil.

19. The conduit of claim 15, wherein at least one of the main member and the at least one side-branch member includes at least one of polytetrafluoroethylene, polyurethane, polyethylene, polyether sulfone, and polyester.

20. The conduit of claim 15, wherein at least one of the main member and the at least one side-branch member includes at least one of a film-tube, extruded tubing, braided tubing, and textile tubing.

21. The conduit of claim 15, wherein at least one of the main member and the at least one side-branch member is treated for at least one of elution of drugs, biocompatibility, radioactivity, and radiopacity.

22. The conduit of claim 15, wherein the side-branch member is configured to be extended through the side opening by a balloon catheter.

23. The conduit of claim 15, wherein at least one of the main member and the side-branch member is kink resistant.

24. A system for implanting a conduit with at least one side-branch in a vessel, comprising:

a main member comprising a wall having an opening; and

at least one side-branch member connected at a proximal end to the main member at the opening, wherein the at least one side-branch member is configured to be extended from within the main member through the opening; and

a delivery system engaging at least one of the main member and the at least one side-branch member for implanting the main member and the at least one side-branch member in the vessel.

25. The system of claim 24, wherein the delivery system includes:

a main guidewire configured to be inserted into the vessel; and

a side-branch guidewire configured to be inserted into a side-branch of the vessel.

26. The system of claim 25, wherein the delivery system further comprises:

a main balloon catheter releasably attachable to the main member and slidably attachable to the main guidewire; and

a side-branch balloon catheter releasably attachable to the at least one side-branch member and slidably attachable to the side-branch guidewire.

27. The system of claim 24, wherein the delivery system includes a deployment tube configured to engage the at least one side-branch member.

28. The system of claim 24, wherein the delivery system includes at least one sheath configured to retain at least one of the main member and the at least one side-branch member.

29. The system of claim 28, wherein the delivery system further includes a push element configured to engage at least one of the main member and the at least one side-

branch member and move the at least one of the main member and the at least one side-branch member with respect to the sheath.

30. The system of claim 28, wherein the sheath has an aperture defined through a wall of the sheath, and the sheath aperture is aligned with the main member opening.

5 31. The system of claim 30, wherein the delivery system further comprises:
a guidewire inserted into a side-branch of the vessel through the sheath aperture
and the main member opening; and
a balloon catheter adapted to be releasably attached to an end of the at least one
side-branch member and advanced over the guidewire.

10 32. The system of claim 24, wherein the delivery system includes at least one
guidewire adapted to be inserted into a vessel.

33. The system of claim 24, further comprising a deployment tube configured to
engage the at least one side-branch member to extend the at least one side-branch member
from within the main member through the opening.

15 34. A method for placing a conduit in a vessel having a vessel side-branch,
comprising:
inserting a main member of the conduit into the vessel;
advancing the main member to a desired location with respect to the vessel side-
branch;

20 extending a side-branch member from within the main member into the vessel
side-branch.

35. The method of claim 34, wherein:
the inserting the main member includes inserting a sheath containing the conduit
into the vessel; and

25 the advancing the main member includes advancing the sheath to the desired
location.

36. The method of claim 34, wherein the extending the side-branch member includes
engaging the side-branch member with a deployment tube.

37. The method of claim 36, wherein the deployment tube includes a hollow interior
30 for accommodating a deployment element.

38. The method of claim 34, wherein:
the inserting the main member includes inserting at least one guidewire into the
vessel; and

the advancing the main member includes advancing the conduit to the desired location over the at least one guidewire.

39. The method of claim 34, wherein extending the side-branch member includes: inserting a guidewire into the vessel;

5 advancing the guidewire through the vessel and through the at least one side-branch member into the vessel side-branch;

placing a balloon catheter on the guidewire;

advancing the balloon catheter along the guidewire to a balloon location within the side-branch member; and

10 extending the side-branch member into the vessel side-branch using the balloon catheter.

40. The method of claim 39, wherein the extending a side-branch member includes engaging the side-branch member with a deployment tube.

41. The method of claim 40, wherein the deployment tube includes a hollow interior

15 for accommodating a deployment element.

1/13

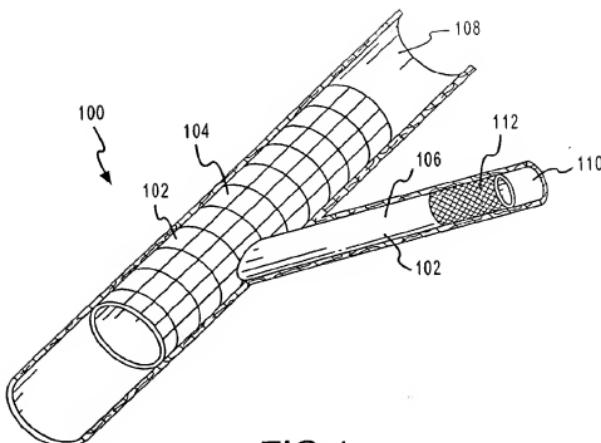


FIG. 1

2/13

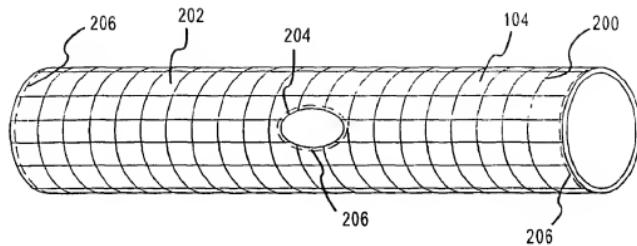


FIG.2

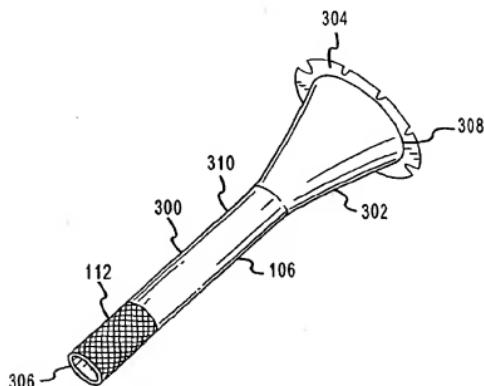
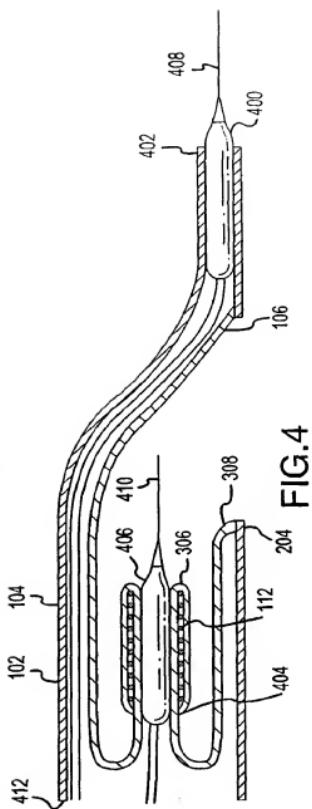


FIG.3



4/13

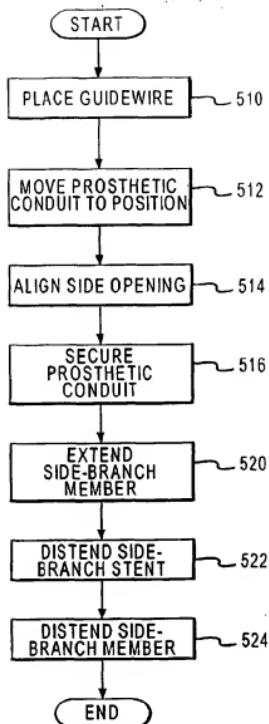


FIG.5

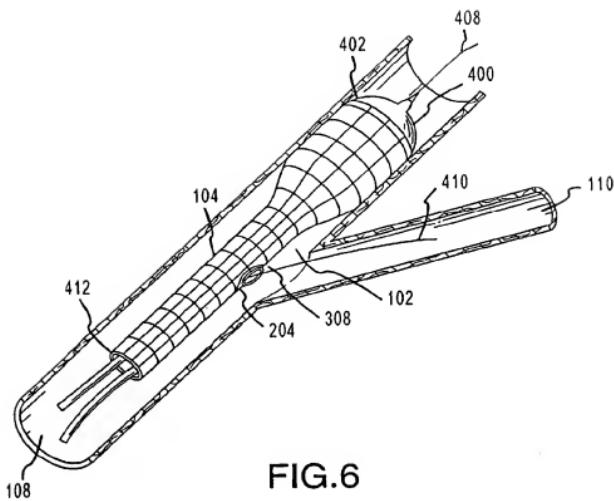


FIG.6

6/13

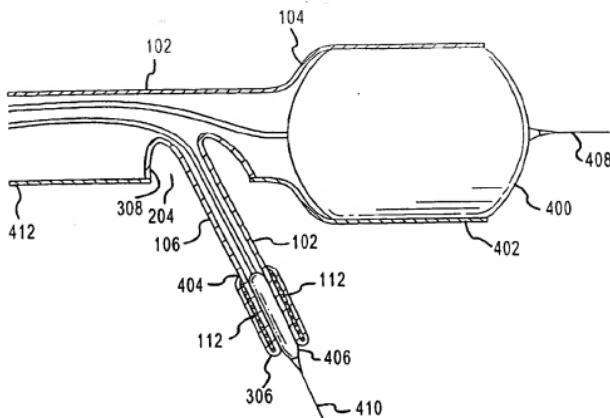


FIG.7

7/13

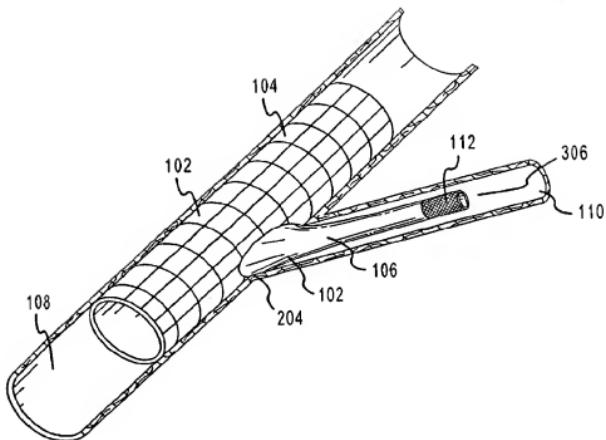


FIG.8

8/13

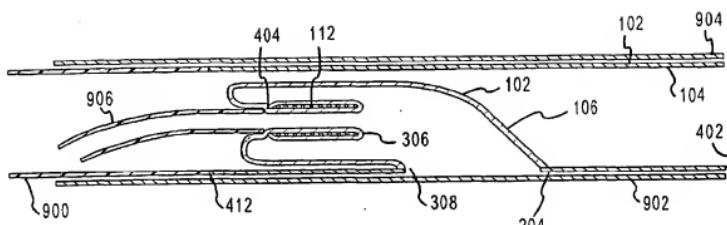


FIG.9

9/13

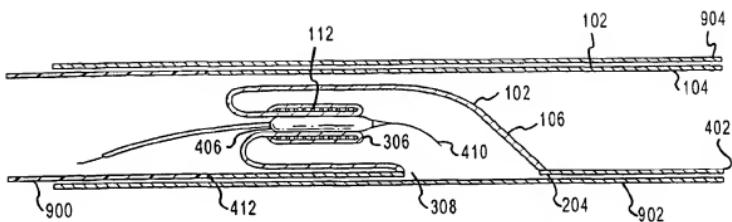


FIG.10

10/13

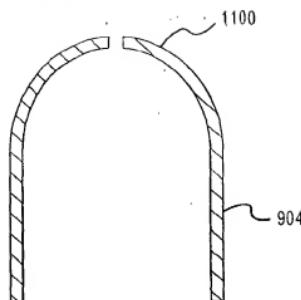


FIG.11

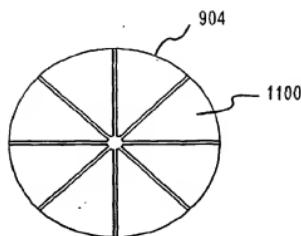


FIG.12

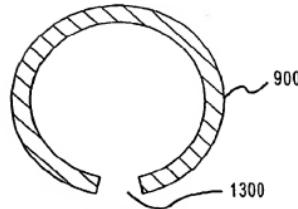


FIG.13

11/13

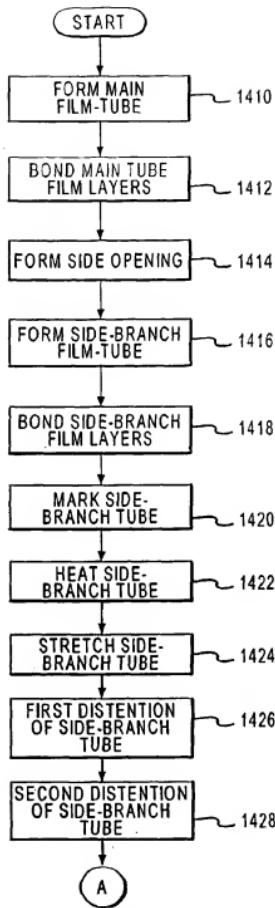


FIG.14A

12/13

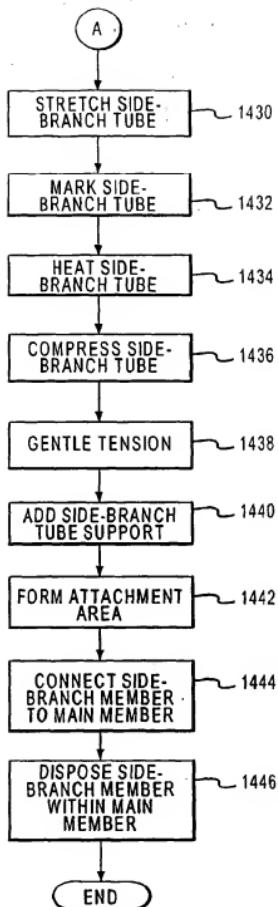


FIG. 14B

13/13

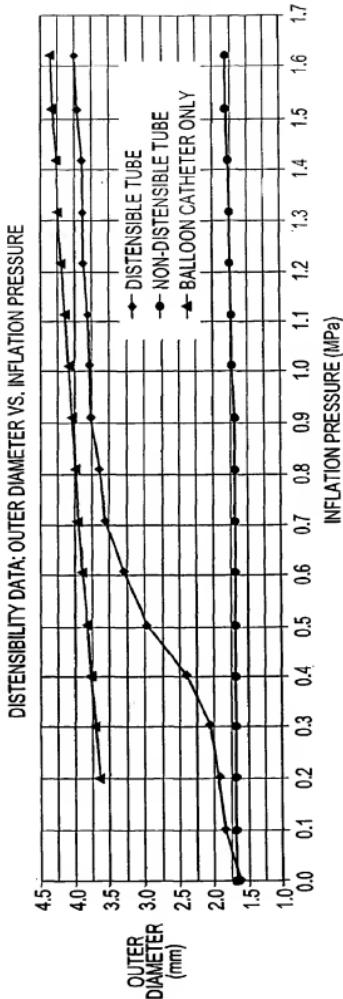


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/01701

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/06.
 US CL : 623/1.1-1.23, 606/191-192, 194-195, 198.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
 U.S. : 623/1.1-1.23; 606/191-192, 194-195, 198.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,984,955 A (WISELINK) 16 NOVEMBER 1999, Figs. 1-3; abstract; line 35, column 3-line 11, column 6.	1-4, 7-12, 15-, 17, 19-20, 22, 24, 27, 32-34, 36-41. ----- 6, 13-14, 18, 23, 28, 29, 35,
X	US 6,059,824 A (TAHERI) 09 MAY 2000, whole document	1-4, 7-8, 15, 24, 34

 Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- *T* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier application or patent published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

E

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

L

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

&

document member of the same patent family

Date of the actual completion of the international search

07 April 2003 (07.04.2003)

Date of mailing of the international search report

28 MAY 2003

Name and mailing address of the ISA/US

 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

Facsimile No. (703)305-3230

Authorized officer

 Vy Q. Bui *Diane Smith*
 Telephone No. 703-306-3420